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10/588,916	07/17/2007	Takafumi Kurosawa	TOS-167-USA-PCT	2935

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EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/588,916	KUROSAWA ET AL.
	Examiner	Art Unit
	TIGABU KASSA	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicant's amendment filed on March 29, 2011 is acknowledged and has been fully considered. **Claims 1 and 4 are pending. Claims 1 and 4 are under consideration in the instant office action.** Claims 2-3 and 5-16 are cancelled. Applicant amended instant claim 1 by incorporating a new limitation reciting "...(d) 0.5-4 wt% of a polyoxyalkylene-modified organopolysiloxane lipophilic active…". Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is FINAL.

Withdrawn objections/rejections

All objections and rejections set forth in the previous office action are hereby withdrawn as per applicant's amendment of the specification updating the first paragraph of the specification and applicant's claim amendment.

Corrected Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Applicant's claim of foreign priority to JP 2004-042231 is GRANTED because the translation of the Japanese language document has been provided.

Other Matters

Applicant's statement disqualifying Nakamura et al., (US 2005/0118211 A1 published on June 02, 2005 with effective filling date of January 18, 2002) as a prior art via citing 35 U.S.C. 103 (c) exclusion statement because of the common assignment at the time of the instant invention with the instant application is acknowledged. As per this statement and the showing of the common ownership Nakamura et al., is hereby removed from the instant rejection set forth below.

New Claim Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

All references are previously cited in the record except Masuda et al., (WO 02/26198, published on April 4, 2002) and Yoneyama et al., (US Patent No. 5362482, published on November 8, 1994).

Claims 1, 4, and <u>newly added claim 17</u> are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari et al., (US 2003/0068348, published on 04/10/03), Tanaka (JP

2001-302455, machine translated, published on 10/31/2001, IDS reference), Masuda et al., (WO 02/26198, published on April 4, 2002), Yoneyama et al., (US Patent No. 5362482, published on November 8, 1994), and Simon (US Patent No. 6346256 published on February 12, 2002).

Applicant Claims

A water-in-oil emulsified sunscreen cosmetic containing the ingredients as recited in the claims.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

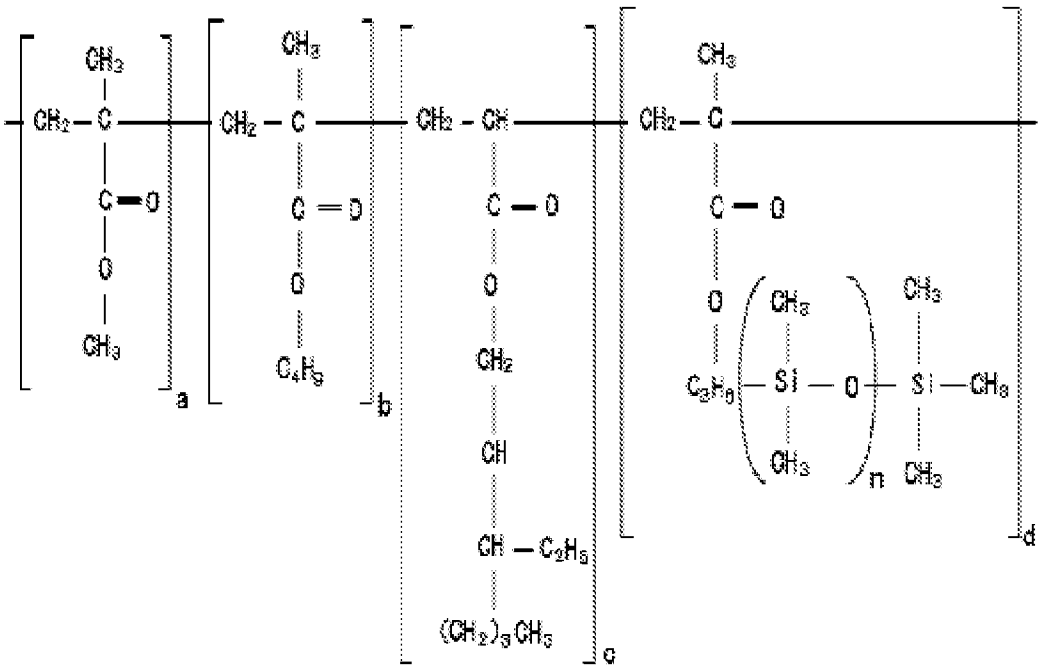
Ferrari et al., teach cosmetic composition, comprising liquid lipid phase containing silicone oil, structured by a combination of polymeric gelling agent and hydrophobic particles (see abstract). Ferrari et al. teach that the solid particles used in the compositions may be fillers or pigments (paragraph 0027). These fillers or pigments may be either hydrophobic or hydrophilic, on condition that they comprise, for example, a hydrophobic outer surface obtained, for example, by coating in a hydrophobic compound forming a hydrophobic film on their surface (paragraph 0033). When the pigments or fillers are hydrophilic, **for example pigments such as zinc oxides**, iron oxides and titanium oxides, **they are coated with a film of hydrophobic compound to introduce them into the liquid fatty phase of the composition of the invention, or they are subjected to a hydrophobic treatment** (paragraph 0050). The coating may comprise a surface treatment of the particles (paragraph 0051). **The coating or surface treatment may be a fluoro coating such as a perfluoroalkyl monoester or diester of phosphoric acid (acid or salt), a perfluoropolyether, a perfluorocarboxylic or perfluorosulphonic acid, or a perfluoroalkyl diethanolamine phosphate salt** (paragraph 0052). **The surface treatment may also be carried out using silicone derivatives, for example grafting with reactive silicones initially comprising hydrogenosilane groups, grafting with a diorganosilane such as dimethylchlorosilane or with an alkylalkoxysilane, grafting with a silane comprising a glycidoxypropyl group, coating with a polyglycerolated silicone, or coating with a silicone-grafted acrylic copolymer or silicone-grafted-polyacrylic** (paragraph 0054). **The liquid fatty phase for example comprises at least 40% and further for example at least 50% by weight of at least one silicone oil** (paragraph 0058). The silicone oils

that may be used in the invention may be **volatile or non-volatile**, linear or cyclic polydimethylsiloxanes (PDMSs), that are liquid at room temperature; polydimethylsiloxanes comprising alkyl, alkoxy or phenyl groups, that are pendent and/or at the end of a silicone chain, the groups each comprising from 2 to 24 carbon atoms; phenylsilicones, for instance **phenyl trimethicones**, phenyl dimethicones, phenyl trimethylsiloxydiphenylsiloxanes, diphenyl dimethicones, diphenyl methyldiphenyl trisiloxanes and 2-phenylethyl trimethylsiloxysilicates (paragraph 0059).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Ferrari et al., teach many of the required components of instant claim 1, Ferrari et al., do not explicitly teach the hydrophobic zinc oxide powder being treated with a combination of specifically by the elected species components of perfluoroalkyl phosphate esters of (a) and the specific acrylsilicone copolymer of structure recited (b). This deficiency is cured by the teachings of Tanaka.

Tanaka teach a cosmetic pigment which permits the employment of a generally used oil, a generally used surfactant etc., and gives moist touch and has an excellent water repellant and oil repellent property and also provide a cosmetic containing the cosmetic pigment (see abstract). Tanaka teaches exactly the same hydrophobic treatment ingredient for the pigments listed in paragraph 0019 which includes flower of zinc treated with both the subgenera of perfluoroalkyl phosphate esters of (a) and the specific acrylsilicone copolymer of structure recited (b) (please see the description and the structure in the abstract).



Although Ferrari et al. teach the incorporation of phenylsilicones, for instance **phenyl trimethicones**, phenyl dimethicones, phenyl trimethylsiloxydiphenylsiloxanes, diphenyl dimethicones, diphenyl methyldiphenyl trisiloxanes and 2-phenylethyl trimethylsiloxysilicates (paragraph 0059), Ferrari et al., do not specifically teach the elected species caprylylmethicone and also the amount recited therein. These deficiencies are cured by the teachings of Simon.

Simon teaches that an oil/water/oil triple emulsion is stabilized with **at least one partially or completely crosslinked organopolysiloxane elastomer having at least one polyoxyethylenated and/or polyoxypropylenated chain** (see abstract). **The amount of the oily internal phase is generally 0.1, 0.5, 1, 5, 10, 15, 20, 25, 30, 35, and 40% by weight, inclusive of all values and subranges therebetween, preferably in the range of from 0.1 to 40% and more preferably from 1 to 25% by weight with respect to the total weight of the triple emulsion** (column 4, lines 39-44). **The oily phase of the O/W primary emulsion and the oily external phase comprise one or more fatty substances chosen from oils of animal origin, oils of vegetable ori**gin (for example, apricot kernel oil, liquid fraction of karite butter), mineral oils (for example, liquid petrolatum), synthetic oils (for example, isohexadecane, hydrogenated polyisobutene or Parleam oil), fluorinated oils, **silicone oils and in particular**

volatile silicone oils, such as octylheptamethyltrisiloxane (or caprylylmethicone) and cyclomethicones, for example cyclopentasiloxane and cyclohexasiloxane, waxes and in particular silicone waxes, silicone gums or silicone resins (column 4, lines 49-58).

Ferrari et al., do not teach the incorporation of polyoxyalkylene-modified organopolysiloxane and its amount as recited in amended claim 1. This deficiency is cured by the teachings of Yoneyama et al.

Yoneyama et al., teach a water-in-oil type emulsified solid composition containing (a) an oil component such as a silicone oil, (b) a solid wax and/or an oil-gelling agent, (c) water, and (d) (i) **a polyoxyalkylene modified organopolysiloxane** or (ii) a lipophilic surfactant and a hydrophobically treated powder, wherein the water content is 5% by weight or more, based upon the total amount of the composition (see abstract). Yoneyama et al., teach in accordance with the present invention, there is also provided a water-in-oil type emulsified solid cosmetic comprising 5% to 85% by weight of an oil component including 30% to 100% by weight, based on the amount of the oil component, of a silicone oil 5% to 20% by weight of an oil-gelling agent, **0.2% to 10% by weight of at least one polyoxyalkylene modified organopolysiloxane** selected from the group consisting of those having the above-mentioned structures (1), (2), (3), and (4), and 5% by weight or more of water, all based on the total amount of the composition (column 3, lines 47-58). Yoneyama et al., teach that the silicone oils usable in the first embodiment of the present invention include those conventionally used in cosmetics compositions (column 4, lines 4-8). Examples of such oils are dialkyl polysiloxanes such as dimethyl polysiloxane, dimethyl cyclopolysiloxane, and diethyl polysiloxane; alkylaryl polysiloxanes such as methylphenyl polysiloxane; diaryl polysiloxane; fatty acid modified polysiloxanes; higher alcohol modified polysiloxanes; amino modified polysiloxane; and **polyoxyalkylene modified organopolysiloxanes** (column 4, lines 9-18). Yoneyama et al., teach their invention provide an emulsified solid cosmetic composition containing **an oil component such as silicone oil and having an excellent stability and good feeling upon application to the skin**(column 2, lines 37-40)

Ferrari et al., do not teach the incorporation of clay specifically the elected species of hectorite treated with benzyl dimethyl stearyl ammonium chloride. This deficiency is cured by the teachings of Masuda et al.

Masuda et al., teach a personal care composition comprising by weight: (a) from about 5% to about 35% of a hydrophobic gel comprising: (i) a cholesteryl derivative; (ii) **an oil swelling clay material**; (iii) **a non-volatile liquid oil**; and (iv) a polar solvent; and (b) a carrier which is substantially free of water, surfactant, and lecithin; which satisfies the need for a personal care composition having improved physical stability (see abstract). Masuda et al., teach that oil swelling clay materials useful herein include hectorite, bentonite, montmorillonite, and bentone clays which have been modified to be compatible with oil (page 4, lines 3-5). **Preferably, the modification is quaternization with an ammonium compound. Preferable oil swelling clay materials include quaternary ammonium modified hectorite**. Commercially available oil swelling clay materials include **benzyldimethyl stearyl ammonium hectorite** with tradename Bentone 38 CG OR available from Rheox. Inc (page 4, lines 5-9). Masuda et al., teach on page 3, lines 24-31 that the oil swelling clay material useful herein **provides the hydrophobic gel together with the cholesteryl derivative, non-volatile liquid oil, and polar solvent. The oil swelling clay material is first swelled with the non-volatile liquid oil prior to mixing with other components for making the hydrophobic gel. Without being bound by theory, it is believed that the oil swelling clay material, while absorbing the non-volatile liquid oil, further holds the closely bonded cholesteryl derivative and polar solvent within its structure**. **The oil swelling clay material functions as a thickener for the composition** (page 3, line 32).

Finding of Prima Facie Obviousness Rationale and Motivation

(MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Ferrari et al., by incorporating hydrophobic zinc oxide powder which is treated with the ingredients as recited in the claim because Tanaka clearly teaches the same hydrophobic treatment ingredient being used for treating pigments like titanium oxide, flower of zinc, etc., which will be incorporated in the

preparation of cosmetic compositions. One of ordinary skill in the art would have been motivated to use such a hydrophobic treatment agent on the pigments because Tanaka teaches such hydrophobically treated pigments pigment permit the employment of a generally used oil, a generally used surfactant etc., and give moist touch and has an excellent water repellant and oil repellent property (see abstract). An ordinary skilled artisan would have had a reasonable expectation of success in combining the teachings of Ferrari et al., and Tanaka because both references teach cosmetic composition containing hydrophobically treated pigments.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Ferrari et al., by incorporating caprylylmethicone because Simon teach the incorporation of caprylylmethicone in cosmetic composition as delineated above as an oil phase. One of ordinary skill in the art would have been motivated to incorporate caprylylmethicone because Simon teach that O/W/O emulsions are also advantageous because of their oily continuous phase, making it possible to form, at the surface of the skin, a lipid film which prevents transepidermal water loss and protects the skin from external attack (column 1, lines 25-30). It must be recognized that the oil-phase can comprise oils such as caprylylmethicone. With regard to the amount Simon teach that **the amount of the oily internal phase is generally 0.1, 0.5, 1, 5, 10, 15, 20, 25, 30, 35, and 40% by weight, inclusive of all values and subranges therebetween, preferably in the range of from 0.1 to 40% and more preferably from 1 to 25% by weight with respect to the total weight of the triple emulsion** (column 4, lines 39-44**).** In the case where the claimed ranges for the amounts of oils such as caprylylmethicone "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Furthermore, a *prima facie* case of obviousness exists since differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical, and it is not inventive to discover the optimum or workable ranges by routine experimentation." (see MPEP 2144.05 and *In re Aller*, 220 F. 2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). An ordinary skilled artisan would have had a reasonable expectation of

success in combining the teachings of Ferrari et al., and Simon because both references teach cosmetic composition containing silicone oils.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Ferrari et al., by incorporating polyoxyalkylene-modified organopolysiloxane in amounts as recited in the amended claim 1 because Yoneyama et al., teach the incorporation of polyoxyalkylene-modified organopolysiloxane in a water-in-oil type emulsified solid cosmetic comprising 5% to 85% by weight of an oil component including 30% to 100% by weight, based on the amount of the oil component, of a silicone oil 5% to 20% by weight of an oil-gelling agent, **0.2% to 10% by weight of at least one polyoxyalkylene modified organopolysiloxane** selected from the group consisting of those having the above-mentioned structures (1), (2), (3), and (4), and 5% by weight or more of water, all based on the total amount of the composition (column 3, lines 47-58). One of ordinary skill in the art would have been motivated to incorporate caprylylmethicone and polyoxyalkylene-modified organopolysiloxane because Simon teach that composition comprising the oily phase such as caprylylmethicone and polyoxyalkylene-modified organopolysiloxane has the advantage of being stable and of being able to retain the activity of active principles, in particular of lipophilic active principles, present in the oily internal phase, whence they are released during the application of the composition to the skin, mucous membranes and/or hair (column 2, lines 25-30). In the case where the claimed ranges for the amounts of ingredients "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Furthermore, a *prima facie* case of obviousness exists since differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical, and it is not inventive to discover the optimum or workable ranges by routine experimentation." (see MPEP 2144.05 and *In re Aller*, 220 F. 2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). An ordinary skilled artisan would have had a reasonable expectation of success in combining the teachings of Ferrari et al., and Yoneyama et al., because both references teach cosmetic composition containing silicone oils.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the instant invention was made to modify the teachings of Ferrari et al., by incorporating hectorite treated with benzyl dimethyl stearyl ammonium chloride clay in the formulation because Masuda et al. clearly teach the incorporation organically modified clays such as hectorite treated with benzyl dimethyl stearyl ammonium chloride. One of ordinary skill in the art would have been motivated to incorporate clays like hectorite treated with benzyl dimethyl stearyl ammonium chloride because as conventionally known by one of ordinary skill in the art such clays are essential to absorb excess oil, dirt, and toxins from the skin while simultaneously exfoliating and improving skin circulation. One of ordinary skill in the art would have been motivated to incorporate clays like hectorite treated with benzyl dimethyl stearyl ammonium chloride because Masuda et al., teach on page 3, lines 24-31 that the oil swelling clay material useful herein **provides the hydrophobic gel together with the cholesteryl derivative, non-volatile liquid oil, and polar solvent. The oil swelling clay material is first swelled with the non-volatile liquid oil prior to mixing with other components for making the hydrophobic gel. Without being bound by theory, it is believed that the oil swelling clay material, while absorbing the non-volatile liquid oil, further holds the closely bonded cholesteryl derivative and polar solvent within its structure**. **The oil swelling clay material functions as a thickener for the composition** (page 3, line 32). An ordinary skilled artisan would have had a reasonable expectation of success in combining the teachings of Ferrari et al., and Masuda et al., because both references teach cosmetic composition containing silicone oils and pigments.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). Applicant is reminded that product-by-process claims are still examined based on the product unless Applicant can show that the process steps impart a structural distinction to the product composition. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusions

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on 571-272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 6/08/11

/CHERIE M WOODWARD/
Primary Examiner, Art Unit 1647